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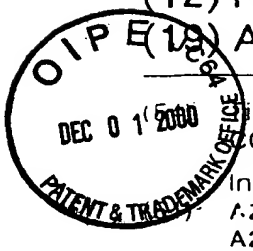
(12) PATENT ABSTRACT (11) Document No AU-A-63136/94
(19) AUSTRALIAN PATENT OFFICE



(54) Title
COLOSTRUM PREPARATION AND STORAGE

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(71) Applicant(s)
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(57) Claim

1. A process for the preparation of a colostrum product which process includes

providing colostrum;

removing or substantially reducing the salt content of said colostrum;

subjecting the colostrum to a bacterial reduction step utilizing centrifugation; and

subjecting the colostrum to a spray drying process.

2. A process for the preparation of a colostrum product which process includes:

providing colostrum;

subjecting the colostrum to a bacterial reduction step utilizing centrifugation;

subjecting the colostrum to an ultra-filtration process; and

subjecting retentate of the ultra-filtered colostrum to a spray drying process.

6. A process as claimed in any preceding claim further including subjecting the colostrum to a pasteurisation process.

NON-CONVENTION

AUSTRALIA

Patents Act 1990

REQUEST FOR A STANDARD PATENT

AND NOTICE OF ENTITLEMENT

The Applicant identified below requests the grant of a patent to the nominated person identified below for an invention described in the accompanying standard complete patent specification.

[70,71]Applicant and Nominated Person:

Minister of Agriculture
19th Floor, Grenfell Centre, 25 Grenfell Street, Adelaide, South Australia, 5000, AUSTRALIA

[54]Invention Title:

COLOSTRUM PREPARATION AND STORAGE

[72]Actual Inventors:

Peter Bennett Duff Whyte

[74]Address for Service:

PHILLIPS ORMONDE & FITZPATRICK
367 Collins Street
Melbourne 3000 AUSTRALIA

[31,33,32] of addition

Applicant states the following:

The nominated person is the assignee of the actual inventor(s)

It is requested that the patent may be granted as a patent of addition to the patent applied for on No. 644468. It is requested that the term be the same as that for the main invention or so much of the term of the patent for the main invention as is unexpired.

The nominated person is not an opponent or eligible person described in Section 33-36 of the Act.

16 May 1994

Minister of Agriculture
By PHILLIPS ORMONDE & FITZPATRICK
Patent Attorneys
By

David B Fitzpatrick

Our Ref : 368662

6000q

NON-CONVENTION

AUSTRALIA

Patents Act 1990

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MINISTER OF PRIMARY INDUSTRIES of 19th Floor, Grenfell Centre, 25 Grenfell Street, Adelaide, SOUTH AUSTRALIA, 5000, AUSTRALIA

[54] Invention Title:

COLOSTRUM PREPARATION AND STORAGE

[72] Actual Inventor(s):

PETER BENNETT DUFF WHYTE

[74] Address for Service:

PHILLIPS ORMONDE & FITZPATRICK
367 Collins Street
Melbourne 3000 Australia

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DATED: 26 May, 1994

MINISTER OF PRIMARY INDUSTRIES
PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:

David B Fitzpatrick

AUSTRALIA

Patents Act

COMPLETE SPECIFICATION
(ORIGINAL)

Class Int. Class

Application Number:
Lodged:

Complete Specification Lodged:
Accepted:
Published:

Priority

Related Art:

Name of Applicant:

Minister of Agriculture

Actual Inventor(s):

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Address for Service:

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Melbourne 3000 AUSTRALIA

Invention Title:

COLOSTRUM PREPARATION AND STORAGE

Our Ref : 368662
POF Code: 114677/115908

The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

This invention relates to a process for the preparation and storage of colostrum products. It is particularly applicable to preparing and storing antibody enriched colostrum without loss of the antibody activity.

Colostrum is the milk secreted by a mammal just before and for a short period after giving birth, containing antibodies to protect offspring against disease. It has been recognised in the prior art that mammals such as cows may be immunized with specific antigens. The antibody enriched colostrum may then be harvested.

A difficulty in the prior art has been that there has been no economical process for preparing and storing colostrum products.

It is known in the prior art that milk products may be spray dried to give a powdered product which may be stored. When known spray drying processes were used to process colostrum it was unexpectedly discovered that the high salt content of the colostrum was a problem which rendered known processes uneconomical.

Colostrum has an extremely high salt content. If known spray drying processes are used to process colostrum the spray drier must undergo extensive cleaning every day for approximately 10 hours to prevent corrosion of the drier. As indicated above this renders the process uneconomic and is a problem which does not relate to normal milk.

Accordingly, it is an object of the present invention to overcome or at least alleviate, one or more of the difficulties related to the prior art.

Accordingly as a first aspect of the present invention there is provided a process for the preparation of a colostrum product which process includes:

providing colostrum;

a process for the preparation of a colostrum product which process includes

providing colostrum;

removing or substantially reducing the salt content of said colostrum;

subjecting the colostrum to a bactofugation step;

and

subjecting the colostrum to a spray drying process.

A further aspect of the present invention provides a process for the preparation of a colostrum product which process includes:

providing colostrum;

subjecting the colostrum to a bactofugation step;

subjecting the colostrum to an ultra-filtration process; and

subjecting retentate of the ultra-filtered colostrum to a spray drying process.

The product so formed is provided in a preserved form without loss of antibody activity. Normal pasteurisation cannot be employed due to the extreme heat sensitivity of immuno-proteins. The bactofugation step reduces the bacterial contamination of the product.

The inventors have found that the step of removal of salt from the colostrum renders the process economic. Salt removal is significant as it reduces the likelihood of corrosion damage to stainless steel plant and reduces the necessity to wet wash drying equipment, offering a significant saving of time and money.

The colostrum may be freshly harvested colostrum or frozen colostrum. The colostrum may be bovine colostrum harvested from freshly calved cows. The colostrum may be harvested using modern milking equipment. The colostrum may be antibody enriched.

The ultra-filtration apparatus preferably removes all molecules of molecular weight less than 20,000 for example water, minerals, salts and non-protein nitrogen. Any suitable ultra-filtration apparatus may be used. In a preferred embodiment a hollow fibre ultra-filtration plant is used. The ultra-filtration step may also remove or reduce the lactose from the content of the colostrum. This is also advantageous from a medical point of view.

In a preferred aspect of the present invention the process may further include the preliminary step of pasteurisation. Low temperature, long time pasteurisation is preferably employed due to the extreme heat sensitivity

of immuno-proteins. In a preferred embodiment the pasteurisation is conducted at approximately 63°C for approximately 30 minutes. The pasteurised colostrum is then preferably cooled to approximately 55°C before undergoing the ultra-filtration step. The pasteurised colostrum may suitably be cooled by regeneration.

In a further preferred aspect of the present invention the process may further include the preliminary step of separating the colostrum. The colostrum may be preferably separated into a light phase (cream) and a heavy phase (skim). The light phase is preferably discarded.

Accordingly yet a further aspect of the present invention provides a process for the preparation of a colostrum product which process includes

providing colostrum;

subjecting the colostrum to a separation step to produce a light phase and a heavy phase;

subjecting the heavy phase colostrum to a bactofugation process;

subjecting the bactofugated colostrum to an ultra-filtration process to remove or substantially reduce the salt content thereof; and

subjecting the filtered colostrum to a spray drying process.

Any suitable separation apparatus may be used. A preferable separation apparatus is a self desludging type apparatus.

The colostrum is preferrably pre-heated to approximately 50°C prior to the separation step. Any suitable means may be used to preheat the colostrum, for example by means of a plate heat exchanger.

In a preferred embodiment it is introduced at a temperature of approximately 55°C to 65°C. A two-fluid nozzle may be used to introduce the concentrate into the drying chamber. In a preferred embodiment, the drying chamber is maintained at approximately 180°C inlet temperature and 70°C outlet temperature. The Applicants have unexpectedly found that this drying technique which

would normally be expected to inactivate the antibodies, has been found by the Applicants not to do so. The energy of the spray drying is taken up as latent heat of evaporation, and accordingly there is very little particle temperature elevation. Accordingly heat damage is minimised. The dried particles preferably fall into a static fluidised bed where further drying and fines agglomeration take place. This produces a product with good dispersibility in water.

It will be understood that the steps of the process of the present invention as described above may take place in any suitable order. Other steps may also be included in the process of the present invention. For example in another preferred embodiment of the present application casein is removed from the milk by precipitation. This step preferably takes place after the colostrum has been subjected to a separation step and the light phase has been discarded.

The present invention will now be more fully described with reference to the accompanying drawings and example. It should be understood, however, that the description following is illustrative only, and should not be taken in any way as a restriction on the generality of the invention described above.

In the drawings:

Figure 1 is a flow diagram of the process according to one embodiment of the present invention.

EXAMPLE 1

Antibody enriched bovine colostrum was harvested from freshly calved cows using modern milking equipment. The colostrum was quickly cooled and held under refrigeration (<4°C) until it was collected. The colostrum was collected daily in a refrigerated van (0°C). Colostrum from individual farms was segregated to prevent cross-contamination.

The colostrum was weighed and tested for microbial quality, inhibitory substances and for specific antibodies to known pathogens. The colostrum was then frozen and stored at -20°C pending the results of these tests.

The frozen colostrum was thawed in a water bath then pooled according to antibody content, to produce a uniform product. The pool was kept refrigerated prior to processing.

The pooled colostrum was pre-heated to 55°C by means of a plate heat exchanger and separated in a self desludging type separator. The light phase (cream) was discarded and the heavy phase (skim) was bactofugated in a bacteria-removing centrifuge.

The skim was passed through a hollow fibre ultra-filtration plant to remove molecules of molecular weight less than 20,000; namely water, lactose, minerals, salts, non-protein nitrogen. The ultra-filtered retentate was preheated to reduce viscosity prior to spray drying.

The concentrate, at 58°C, was introduced into a spray drying chamber of aseptic design with hepa filters in the feed line, atomising air, and drying air supply, purpose built for pharmaceutical grade products. The drying chamber was maintained at 180°C inlet temperature and 70°C outlet temperature. The dried particles fell into a static fluidised bed where further drying and fines agglomeration took place, producing a product with good dispersibility in water. The finished product was then packaged.

EXAMPLE 2

Antibody levels and quantities of colostrum collected from cows varies dramatically over the first week after calving. The colostrum from the first six milking was collected. For practical handling reasons all milk collected on one day was pooled at each farm with each farms milk kept separate by collection date. Each of these farm's milk deliveries was kept separate and assessed individually for quality. Colostrum quality was shown to be satisfactory with respect to microbial and inhibitory substances tests, and pooled on the basis of quantity (batch size) and antibody titre to produce a standard, weighted average antibody titre to a known pathogen. This pooling step ensured that a standard

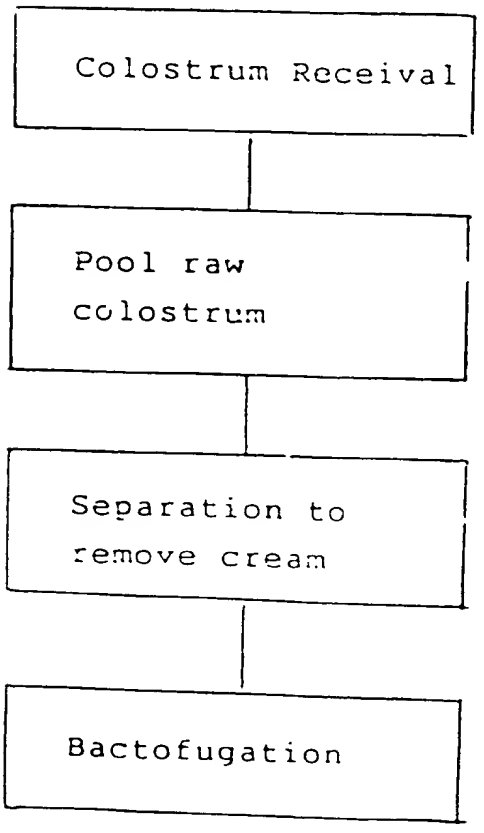
product was consistently produced with respect to both the colostrum composition and antibody potency.

Approved colostrum was pooled for processing so as to provide correct antibody levels in the final powder product. The pooled colostrum was processed by skimming in a cream separator to reduce fat, bactofugation to reduce microbiological load, ultra filtration to concentrate protein and reduce lactose and mineral levels, including salt, and spray drying in an aseptic, pharmaceutical model spray drier with filtered air supply. Powder was packed in new food grade poly-ethylene bags with new fibre-board containers and sealed for transport.

Table 2 illustrates a production flow chart.

TABLE 2

Production Flow Chart:

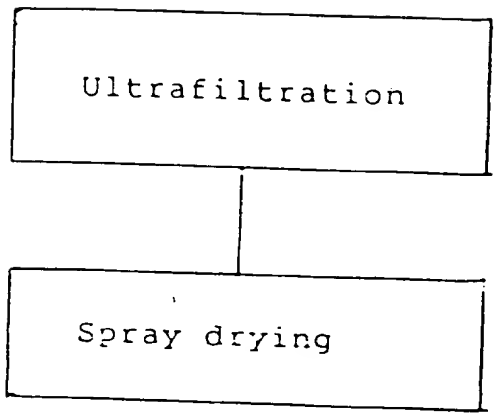


Raw colostrum is received, weighed and stored pending quality control and release.

Approved milk is pooled according to age and potency to produce a homogeneous batch of standard potency.

Cream (milk fat) is removed by separation in a standard dairy separator

The skim colostrum is centrifuged to eliminate pathogens and reduce total microbial load



Product is concentrated by reduction of water, lactose and electrolyte levels through ultrafiltration membranes. Salt content is reduced during this process.

Product is spray dried in an aseptic spray drier.

EXAMPLE 3

Table 3 lists the constituents of a sample of colostrum product which has been prepared by the process of Example 1.

TABLE 3

	Colostrum Product Prepared by Process of Example 1
Moisture %	5.0
Fat %	2.7
Solubility Index	0.1
Sc.Pts./Ext. Matter	A
Protein (TN x 6.38)%	71.0
Lactose %	14.3
Ash % @ 500°C	4.0
Salt %	0.48
Whey Protein Nitrogen mg/g	>7.0
Dispersability %	56
Wettability (Secs) @ 25°C	60+, 60+, 60+
Aluminium mg/kg	3.4
Penicillin	<0.0025
Other Inhibitory Substances (As Penicillin I.U./mL) (I.U./mL)	<0.0025

The above process reduces salt content by approximately 25%. First colostrum contains approximately 32 mmol/L of NaCl. If concentrated 7 fold using conventional means, the salt content of the powder would be 217 mmol/kg, which is equivalent to 1.25% of the total weight. This concentration of salt could seriously effect the stainless steel surfaces of the spray drier.

The process described reduces the salt content from 1.25% to less than 0.94% of the final powder, significantly reducing the risk of corrosion, and negating the need for frequent wet cleansing procedures as described.

For pooled colostrum (milkings 1-6, skimmed) the process reduces salt content by approximately 59%. Pooled colostrum contains approximately 22 mmol/L of NaCl. If concentrated 9 fold using conventional means, the salt content of the powder would be 199 mmol/kg, which is equivalent to 1.15% NaCl of the total weight.

The process described reduces the salt content from 1.15% to less than 0.47% NaCl of the final powder, significantly reducing the risk of corrosion and negating frequent wet cleansing procedures.

Finally, it is to be understood that various other modifications and/or alterations may be made without departing from the spirit of the invention as outlined herein.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A process for the preparation of a colostrum product which process includes

providing colostrum;

removing or substantially reducing the salt content of said colostrum;

subjecting the colostrum to a bacterial reduction step utilizing centrifugation; and

subjecting the colostrum to a spray drying process.

2. A process for the preparation of a colostrum product which process includes:

providing colostrum;

subjecting the colostrum to a bacterial reduction step utilizing centrifugation;

subjecting the colostrum to an ultra-filtration process; and

subjecting retentate of the ultra-filtered colostrum to a spray drying process.

3. A process as claimed in claim 2 wherein a hollow fibre ultra-filtration apparatus is used.

4. A process as claimed in claim 2 or claim 3 wherein said ultra-filtration process removes substantially all molecules of molecular weight less than about 20,000.

5. A process as claimed in any preceding claim wherein the ultra-filtration process removes and reduces the lactose content of the colostrum.

6. A process as claimed in any preceding claim further including subjecting the colostrum to a pasteurisation process.

7. A process according to any one of claims 2 to 6 wherein the bacterial reduction step takes place prior to the ultra-filtration process.

8. A process as claimed in any preceding claim wherein the process includes a step of separating the colostrum into a light phase and a heavy phase.

9. A process as claimed in claim 8 wherein said light phase is discarded.

10. A process as claimed in claim 8 or claim 9 wherein the separation step takes place prior to the bacterial reduction step.

11. A process substantially as hereinbefore described with reference to any one of the examples or drawing.

12. a colostrum product produced by the process of any preceding claim.

DATED: 16 May, 1994

PHILLIPS ORMONDE & FITZPATRICK

Attorneys for:

~~MINISTER OF AGRICULTURE~~

David B Fitzpatrick

5890G

ABSTRACT

A process for the preparation of a colostrum product which process includes

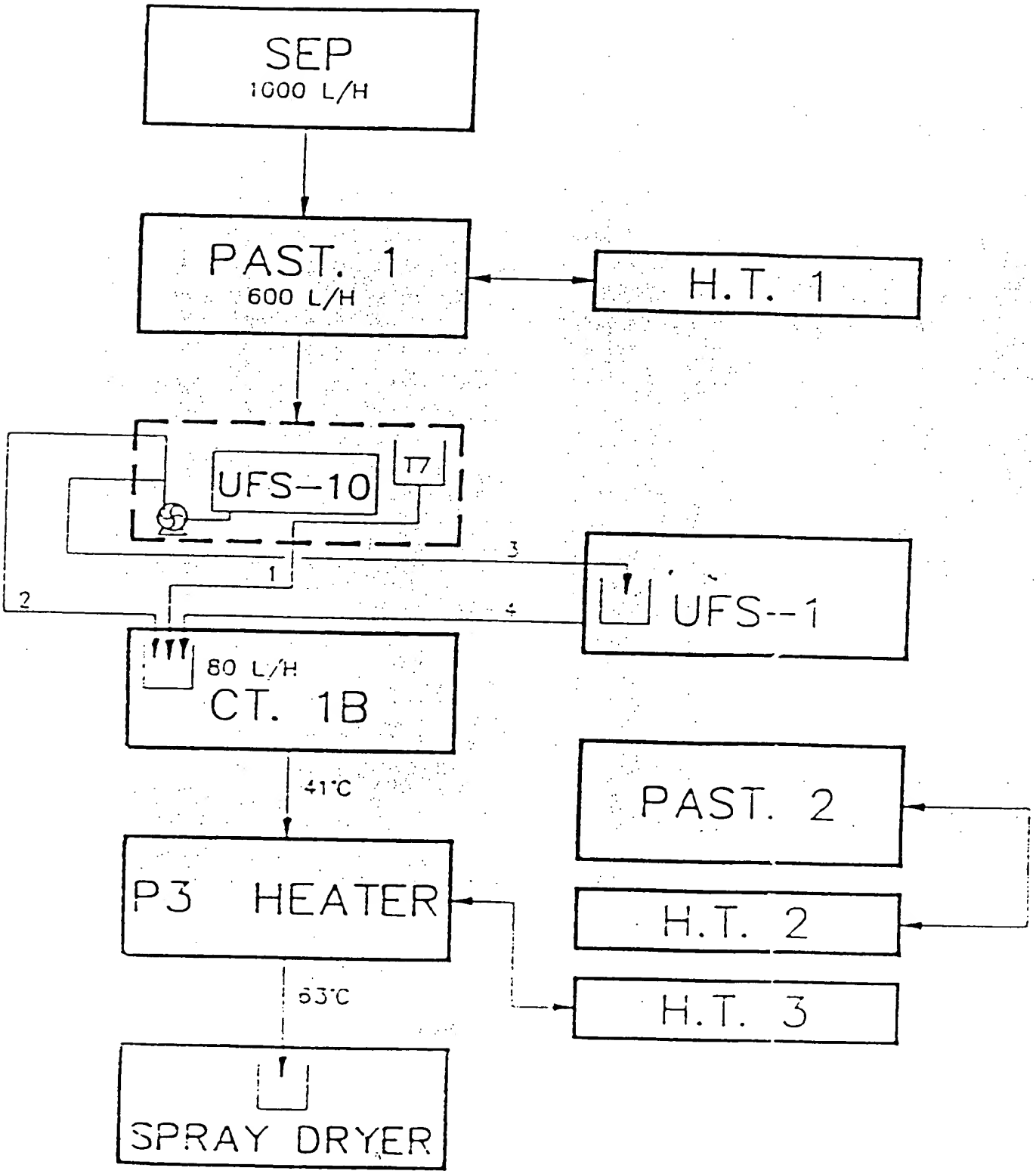
providing colostrum;

removing or substantially reducing the salt content of said colostrum;

subjecting the colostrum to a bacterial reduction step utilizing centrifugation; and

subjecting the colcstrum to a spray drying process.

Figure 1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H.T. 2
63°C
H.T. 3
SPRAY DRYER